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|  | MBi NUTRACEUTICALS | STANDARD OPERATING PROCEDURE CONFIDENTIAL | SOP NUMBER/RELEASE EQ-006 / 6 |
| TITLE: GENERAL CLEANING PROCEDURE FOR EQUIPMENT | | | PAGE NUMBER 1 of 4 |

SOP COVER PAGE

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| AUTHOR: | Signed: _____ Date: _____ | | |
| | Kimberly Griffin, QA Manager | | |
| APPROVED BY: | Signed: _____ Date: _____ | | |
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| | Jeff Jensen, VP/Business Development | | |
| EFFECTIVE DATE: | 2/20/2023 | SUPERSEDES VERSION: | EQ-006 Release 5 1/27/22 |
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| If the SOP is reviewed and there are no changes (i.e. if it is not revised) then a signature and date (below) indicate the review has occurred. If a revision is required, a new version is released and the signature/date (below) does not need to be completed. | | | |
| Review Date: | | Signature: _____ | |
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| Review Date: | | Signature: _____ | |

Approval of this page indicates approval of all pages in this procedure.

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|---|------------------------------|--|----------------------------------|
|  | MBi NUTRACEUTICALS | STANDARD OPERATING PROCEDURE CONFIDENTIAL | SOP NUMBER/RELEASE EQ-006 / 6 |
| TITLE: GENERAL CLEANING PROCEDURE FOR EQUIPMENT | | | PAGE NUMBER 2 of 4 |

1. PURPOSE

- 1.1. This Standard Operating Procedure (SOP) defines general procedures for equipment and utensil cleaning.

2. SCOPE

- 2.1. This SOP is limited to the general cleaning procedure for manufacturing equipment and utensils at MBI. Equipment with specific cleaning procedures will have those procedures outlined in their Cleaning and Operation SOP and are not covered in the scope of this SOP.

3. RESPONSIBILITIES


- 3.1. Manufacturing Supervisor:
 - 3.1.1. Acts as oversight for developing, revising, and maintaining this SOP
 - 3.1.2. Ensures that employees that clean equipment are trained on this SOP
 - 3.1.3. Ensures all employees compliance with this SOP
- 3.2. Manufacturing Employees:
 - 3.2.1. Comply with the procedures of this SOP
 - 3.2.2. Provide input for developing, revising, and maintaining this SOP
 - 3.2.3. Ensure compliance of all employees to this SOP
- 3.3. Warehouse Manager:
 - 3.3.1. Acts as oversight for developing, revising, and maintaining this SOP
 - 3.3.2. Maintains service and cleanliness of equipment
 - 3.3.3. Ensures compliance of all employees to this SOP

4. REFERENCES

- 4.1. Standard Operating Procedures for specific equipment cleaning
- 4.2. SOP EQ-034 Hygiene Ensure Luminometer
- 4.3. Utah Department of Agriculture, Quaternary Ammonium, Why Use Test Strips?
<https://ag.utah.gov/wp-content/uploads/2021/02/Sanitizers-Quaternary-Ammonium.pdf>

5. MATERIALS AND EQUIPMENT

- 5.1. Liquid Soap (Such as Dawn)
- 5.2. Rag
- 5.3. Liquid WAXIE Solution 910 FINALE FS No Rinse Sanitizer
- 5.4. Scouring pads (Scotch-Brite or similar)
- 5.5. Hygiene Ensure monitor
- 5.6. Hygiene Ultrasnap ATP surface swab
- 5.7. Yellow 5 gallon buckets


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|---|------------------------------|--|----------------------------------|
|  | MBI NUTRACEUTICALS | STANDARD OPERATING PROCEDURE CONFIDENTIAL | SOP NUMBER/RELEASE EQ-006 / 6 |
| TITLE: GENERAL CLEANING PROCEDURE FOR EQUIPMENT | | | PAGE NUMBER 3 of 4 |

6. SAFETY REQUIREMENTS

- 6.1. Employees that clean equipment must wear at a minimum: hair coverings, facial hair cover (if applicable), lab coat or similar body cover suit and gloves.

7. PROCEDURE

- 7.1. Equipment used in manufacturing or packing products shall be cleaned directly after use. If the equipment is not used for longer periods of time, they should be cleaned again to eliminate dust that may have accumulated on it since it was last used, and to allow it to pass Hygiene surface swab testing, if applicable.
- 7.2. Yellow 5 gallon buckets are designated for sanitation purposes only.
- 7.3. To clean manufacturing and production equipment with soap and water:
 - 7.3.1. Using scouring pads and hot soapy water, cover all surfaces of the equipment and scrub.
 - 7.3.2. Rinse the equipment thoroughly with water.
 - 7.3.3. Visually inspect the equipment. The equipment surfaces should be free of soap residue, bubbles, film, rouge, discoloring, rust, or foreign material. Equipment should be visually clean, and extra care taken to inspect hard to view areas.
 - 7.3.4. If the equipment fails visual inspection, repeat steps 7.2.1 to 7.2.3. The equipment may not be used until it passes visual inspection.
- 7.4. To sanitize equipment with WAXIE 910 No Rinse Sanitizer following cleaning:
 - 7.4.1. Waxie Solution Station dispenser is used to dispense the correct amount of Waxie 910 concentrate and water. A minimum of once per quarter, the dispensed solution should be tested to confirm that the correct amount of ammonium is in the solution.
 - 7.4.1.1. Tear off a two-inch strip of Hydrion QT-40 paper, and immerse in the prepared Waxie 910 solution for ten seconds. Compare the test strip to the color guide on the package.
 - 7.4.1.2. Record the concentration on the Waxie 910/Bleach log page.
 - 7.4.1.3. The concentration should be about 200 ppm. If it is higher than that, the solution should be diluted and retested until the test strip reads 200 ppm. If the concentration is measuring lower than 200 ppm, additional concentrate should be added until the solution measures at 200 ppm.
 - 7.4.1.4. If the Waxie Solution Station is dispensing the solution at an incorrect concentration, then Waxie customer service should be called to request maintenance.
 - 7.4.1.5. While the Waxie Solution Station is dispensing the solution at an incorrect concentration, the solution should be tested and corrected according to the directions in 7.3.1.3 every time it is prepared.
 - 7.4.1.6. After the Waxie Solution Station has been serviced for a malfunction affecting the Waxie 910 concentration, the ammonium concentration should be tested weekly until three consecutive 200 ppm measurements are taken, prior to resuming monthly or quarterly testing.
 - 7.4.2. Spray or submerge the equipment thoroughly with WAXIE 910.

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|  MBI NUTRACEUTICALS | STANDARD OPERATING PROCEDURE CONFIDENTIAL | SOP NUMBER/RELEASE EQ-006 / 6 |
| | TITLE: GENERAL CLEANING PROCEDURE FOR EQUIPMENT | PAGE NUMBER 4 of 4 |

- 7.4.3. Allow the surface to remain in contact with the sanitizer for 10 minutes. Let air dry.
- 7.4.4. If applicable, test surfaces of the equipment with Hygiena Ensure Luminometer, according to the procedure in SOP EQ-034.
- 7.4.5. If the equipment fails the Hygiena test, repeat steps 7.2 and 7.3.2 through 7.3.4. The equipment may not be used until it passes Hygiena testing.
- 7.5. Large drums and kettles should be nested, covered, or inverted to prevent dust accumulation on interior surfaces until immediately before use.
- 7.6. Verification of equipment cleaning and sanitization is recorded in the batch record prior to equipment use with a product.
- 7.7. Packaging personnel should sign off on the packaging record that accompanies the equipment that the equipment has been cleaned prior to use.
- 7.8. General Production Area Housekeeping
 - 7.8.1. Only one batch of product shall be in the packing or manufacturing area at any given time.
 - 7.8.2. All labels, closures, and products relating to that batch must be put away properly before another batch of product can be brought to the area.

8. RECORDS, REPORTS, AND FORMS

- 8.1. Packaging Cleaning and Use Log Books
- 8.2. Batch Production Records
- 8.3. Hygiena Suretrend Software
- 8.4. Waxie 910/Bleach Log: (H:) / Lab / Documents / Charts / Waxie910_Bleach ppm log.doc

9. HISTORY

| RELEASE NO. | EFFECTIVE DATE | REASON/JUSTIFICATION FOR CHANGE |
|-------------|----------------|--|
| 1 | 08/01/05 | New |
| 2 | 03/15/2006 | Format SOP and update for consistency |
| 3 | 03/04/2010 | Added special instructions for protecting critical surfaces from contamination when not in use, including wrapping surfaces in plastic and nesting, covering, or inverting drums and kettles. |
| 4 | 04/03/2019 | 9.4 & 9.10 Replace Bleach with WAXIE 910 QUATERNARY. Addition of Hygiena Ensure Luminometer testing. |
| 5 | 1/27/22 | Removed unnecessary definitions. Updated cleaning procedure to reflect current practice. Removed high pressure steam cleaner, and DI water for cleaning. Added steps for testing Waxie 910 concentration, logging. |
| 6 | 2/20/2023 | Update QA Manager. Added Yellow 5 gallon buckets to the material list and procedure. |